

DRAFT

ORTHOPAEDIC AND REHABILITATION DEVICES PANEL
of the
MEDICAL DEVICES ADVISORY COMMITTEE

Gaithersburg Marriott
Salons A, B, C, and D
9751 Washingtonian Boulevard
Gaithersburg, Maryland
June 2, 2004

Panel Chairperson

Michael J. Yaszemski, M.D., Ph.D.

Executive Secretary

Janet L. Scudiero, M.S., acting

10:00 am Call to Order
Conflict of Interest and Deputization to Voting Member Status Statements
Panel Introductions
Update since the December 11, 2003 Meeting

DePuy Spine, Inc., Charité Artificial Lumbar Disc, P040006

10:15 am 1st Open Public Hearing*

10:45 am Sponsor Presentation

11:45 am FDA Presentation

12:30 pm Lunch

1:30 pm Panel Deliberation and FDA Questions

3:30 pm 2nd Open Public Hearing

4:00 pm Break

4:15 pm FDA and Sponsor Summations, up to 15 minutes each

4:45 pm Panel Vote

6:00 pm Adjournment

* **Open Public Hearings** – Interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair may ask them to remain if the panel wishes to question them. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.